

ORGANIZATION
OF TERATOLOGY
INFORMATION
SERVICES

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Ms. Toni Stifano
Dockets Management Branch (HFA-9059)
Food and Drug Administration
5630 Fisher Lane Room 1061
Rockville, MD 20857

August 24, 1999

Dear Ms. Stifano,

This letter is written in response to the call for comments on the following **draft** document: "Reviewer Guidance: Evaluation of Human Pregnancy Outcome Data", Docket 99-D-1540.


The Executive Committee of the Organization of Teratology Information Services (OTIS) supports the drafts and believes this document should become the-standard for investigators studying the effects of environmental exposures and potential risks to the mother and fetus.

Omitted, however, is the vital need for long-term follow-up and diagnosis of defects not seen at birth. It is well known that one-half or more of all birth defects are diagnosed after the neonatal period. An example would be third trimester maternal use of streptomycin and hearing loss in children, not usually diagnosed until later.

With inclusion of long-term follow-up, these documents are not only excellent guidelines for industry, but have the opportunity to become primary "tools" for students, educators and investigators trying to understand the complicated issues of evaluating human studies of pregnancy outcomes.

All involved in creation of these documents are to be commended.

Sincerely,


Dee Quinn
President

Gerald Briggs Robert Felix Sandra Gangell Janine Polifka Julia Robertson Lori Wolfe
Member at Large Secretary Past President Member at Large Member at Large Treasurer

99D-1541

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Ms. Toni Stifano

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Docket 99-D-1540

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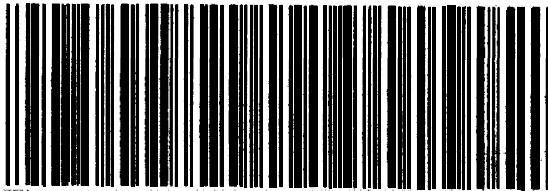
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